K122925

510(k) SUMMARY
(as required by 807.92(c))

FEB 1 2 2013

Regulatory Correspondent:

AJW Technology Consultants, Inc
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Apollo Beach, FL 33572
John O'Brien
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Submitter of 510(k):

New Stetic
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Date of Summary: September 11, 2012

Trade/Proprietary Name: New Stetic Artificial Teeth

Classification Name: Denture, Plastic, Teeth

Product Code: ELM

Intended Use: A preformed plastic denture tooth is a prefabricated device, composed of materials such as methyl methacrylate, that is intended for use as a tooth in a denture.

Device Description: The New Stetic Acrylic Teeth are made of acrylic resin; the teeth come in various shades and sizes to fit the requirements of the specific patient.

Predicate Device: K931162 – King Dental Corp – King-Hue, Royal Coral, Super-C Artifical Teeth

Technological Characteristics and Substantial Equivalence:	New Stetic claims the proposed devices to be substantially equivalent to the devices previously cleared by FDA in K931162. New Stetic claims this equivalence because the proposed devices have an equivalent intended use, manufacturing materials, operating principles and physical operational specifications as compared to the predicate devices. There are no differences between the New Stetic Artificial Teeth K122925 and the King Dental Artificial Teeth K931162 with respect to indications for use or technology.
Performance Testing:	Performance testing was completed to ISO 22112 First edition 2005-11-01, Dentistry -- Artificial teeth for dental prostheses. (Dental/ENT).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2013

New Stetic
C/O Mr. John O'Brien
Regulatory and Quality Systems Lead
AJW Technology Consultants, Incorporated
445 Apollo Beach Boulevard
APOLLO BEACH FL 33572

Re: K122925
Trade/Device Name: New Stetic Artificial Teeth
Regulation Number: 21 CFR 872.3590
Regulation Name: Preformed Plastic Denture Tooth
Regulatory Class: II
Product Code: ELM
Dated: January 10, 2013
Received: January 25, 2013

Dear Mr. O'Brien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122925

Device Name: New Stetic Artificial Teeth

A preformed plastic denture tooth is a prefabricated device, composed of materials such as methyl methacrylate, that is intended for use as a tooth in a denture.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.02.06 08:22:07 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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